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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,544

12/14/2005

Breda Mary Cullen

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EXAMINER

WESTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,544	<b>Applicant(s)</b> CULLEN ET AL.	
	<b>Examiner</b> Nissa M. Westerberg	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 5 - 13, 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5 - 13, 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 1, 2009 has been entered.

### ***Comments and Notes***

2. In the listing of claims filed April 1, 2009, the status of claim 20 is identified as previously presented. Claim 20 is a new claim but the subject matter contained therein was present in previously presented but now cancelled claim 15.

3. It is kindly suggested that applicant use "antioxidant dyestuff" in place of "antimicrobial" in line 7 of claim 1 and the composition is defined in line 2 of the claim as containing an antioxidant dyestuff which is an antimicrobial, rather than as containing an antimicrobial.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 – 3 and 12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 13 of copending Application No. 11/608553 in view of Partain. This rejection is MAINTAINED for the reasons of records set forth in the Office Action mailed May 13, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that the two applications are not commonly owned and thus grounds of the rejection is improper.

This is not found to be persuasive. For a double-patenting rejection to be proper, the instant application and the other application or patent must have either a common inventor and/or a common assignee/owner (See MPEP 804). While the two applications may not have a common owner, they do have a common inventor and the rejection is therefore proper.

6. Claims 1 and 8 – 10 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 4, 7 – 13, 20 and 21 of copending Application No. 10/579850. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 13, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that the two applications are not commonly owned and thus grounds of the rejection is improper.

This is not found to be persuasive. For a double-patenting rejection to be proper, the instant application and the other application or patent must have either a common inventor and/or a common assignee/owner (See MPEP 804). While the two applications may not have a common owner, they do have a common inventor and the rejection is therefore proper.

7. Claims 1 and 11 – 13 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 18 of copending Application No. 10/579897. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 11 – 13 and 20 are generic to all that is recited in claims 1 – 18 of US'897. That is, claims 1 – 18 of US'897 falls entirely within the scope of claims 1 and 11 – 13 and 20 or, in other words, claims 1 and 11 – 13 and 20 are anticipated by claims 1 – 18 of US'897. Specifically, the claims of US'897 recite a wound dressing material comprised of a medically acceptable polymer such as oxidized regenerated cellulose (§ [0027]), a wound healing therapeutic agent such as antimicrobial agent (claim 14) or antioxidant dyestuff (claim 15). The instant claims recite compositions of oxidized cellulose and an antimicrobial dyestuff.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Terminal Disclaimer***

8. The terminal disclaimers filed on April 1, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 10/528262 or any patent granted on Application Number 10/579850 has been reviewed and is accepted. The terminal disclaimers have been recorded.

***Claim Rejections - 35 USC § 112 – 2<sup>nd</sup> Paragraph***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 5 – 13 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Lines 6 – 7 contain the limitation “allows sustained release of effective amounts of the antimicrobial”. In this claim, the antioxidant dyestuff is an antimicrobial. Because the antimicrobial compound also has antioxidant and dye effects, it is unclear if the “effective amount” of the compound recited in lines 6 – 7 must be an antimicrobially effective amount, an antioxidant effective amount and/or a dye effective amount. Please clarify.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



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14. Claims 1, 5, 6 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. (EP 0368253) in view of Rosenthal et al. (US 5,565,210). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 13, 2008 and those set forth below.

Applicant traverse this rejection on the grounds that neither reference discloses a wound dressing material comprising oxidized cellulose dyed with an antioxidant dyestuff wherein the antioxidant dyestuff is antimicrobial and the dyestuff is bound to the surface of the solid bioabsorbable substrate and allows sustained release of effect amounts of the antimicrobial.

These arguments are not persuasive. The material described by the instant claims and the cited prior is comprised of oxidized cellulose and an antioxidant dyestuff. As described in the instant specification (§ [0015] of the PGPub of the instant application), the sustained release of the antioxidant dyestuff is accomplished by the gradual breakdown of the bioabsorbable material, in this case the oxidized cellulose. In both the cited prior art and the instant application, the antioxidant dyestuff is added to the other ingredients in an aqueous solution that is further processed into a solid material (§§ [0071] – [0072] of the instant application; and Examples 4 and 5, for example, of Partain et al. (col 15, ln 16 – col 16, ln 9). The properties of a material or composition cannot be separated from the material or composition itself. As both the cited prior art and the instant claims recite a solid bioabsorbable substrate comprised of oxidized cellulose and an antioxidant dyestuff, the material of the cited prior art must

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necessarily contain the antioxidant dyestuff bound to the surface of the solid substrate and allow for sustained release of effective amounts of the antimicrobial.

15. Claims 1, 5 – 7, 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. and Rosenthal et al. further in view of Fowler et al. (US 5,667,501). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 13, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Fowler et al. does not cure the deficiency of Partain and Rosenthal to teach a wound dressing material comprising oxidized cellulose dyed with an antioxidant dyestuff wherein the antioxidant dyestuff is antimicrobial and the dyestuff is bound to the surface of the solid bioabsorbable substrate and allows sustained release of effect amounts of the antimicrobial.

These arguments are not persuasive. As discussed in greater detail above, the material taught by Partain and Rosenthal necessarily has the antioxidant dyestuff bound to the surface of the solid substrate and allows for sustained release of effective amounts of the antimicrobial. Fowler et al. is therefore not required to cure the deficiency and this rejection is maintained.

16. Claims 1, 5 – 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Rosenthal et al. and Fowler et al. further in view of Nimrod et al (WO 87/05517). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 13, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Fowler et al. does not cure the deficiency of Partain and Rosenthal to teach a wound dressing material comprising oxidized cellulose dyed with an antioxidant dyestuff wherein the antioxidant dyestuff is antimicrobial and the dyestuff is bound to the surface of the solid bioabsorbable substrate and allows sustained release of effect amounts of the antimicrobial.

These arguments are not persuasive. As discussed in greater detail above, the material taught by Partain and Rosenthal necessarily has the antioxidant dyestuff bound to the surface of the solid substrate and allows for sustained release of effective amounts of the antimicrobial. Nimrod et al. is therefore not required to cure the deficiency and this rejection is maintained.

17. Claims 1, 5 – 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Rosenthal et al. and Fowler et al. further in view of Gibbins (US 6,355,858). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 13, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Fowler et al. does not cure the deficiency of Partain and Rosenthal to teach a wound dressing material comprising oxidized cellulose dyed with an antioxidant dyestuff wherein the antioxidant dyestuff is antimicrobial and the dyestuff is bound to the surface of the solid bioabsorbable substrate and allows sustained release of effect amounts of the antimicrobial.

These arguments are not persuasive. As discussed in greater detail above, the material taught by Partain and Rosenthal necessarily has the antioxidant dyestuff bound

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to the surface of the solid substrate and allows for sustained release of effective amounts of the antimicrobial. Gibbins et al. is therefore not required to cure the deficiency and this rejection is maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Jake M. Vu/

Examiner, Art Unit 1618

NMW